

REMARKS

In the Office Action mailed August 4, 2004, the Examiner rejected claims 1 to 14. This Amendment "B" cancels no claims, amends claims 1 and 12 to 14, and adds no new claims. Accordingly, claims 1 to 14 remain pending in this application.

Claims 1 to 5 and 12 to 14 were rejected under 35 U.S.C. 103(a) as unpatentable over Vandehey (US 4,919,414) in view of KenKnight et al. (US 6,112,117).

In the Examiner's "Response to Arguments", the Examiner refers to the right hand side of Figure 6 of Vandehey which is alleged to show the first threshold (93), second threshold (91) and gradient (95) that remains within limits (87, 89). Applicant strongly disagrees with this interpretation. First, reference number 95 does not refer to a gradient but to a threshold value (see col. 8, line 7 onwards). Mathematically, a gradient is a slope, characterized by an angle to the horizontal or x-axis. Second, in the present invention as claimed, the gradient, i.e. the slope, of the signal between the first and second thresholds has to remain within certain limits. The important point is that these limits are gradient limits as indicated, for example, by the inclined parallel dotted lines on Figure 9 of the present application. This point has been clarified in claims 1 and 13.

The limits (87, 89) referred to by the Examiner are signal amplitude limits, not gradient limits. Admittedly the signal between the two points (91, 93) will have a gradient, but it is unrelated to the signal amplitude limits (87, 89). In fact, the latter, being parallel to the x-axis, have a gradient of zero, so it is clear that the gradient of the signal between the points (91, 93), whatever it is but it is clearly not zero, cannot lie within the limits of the gradients of the signal amplitude limits (87, 89).

In fact, nowhere in Vandehey is there any suggestion or indication that the gradient between the maxima and minima of the ECG signal is of any interest in determining the instant of defibrillation or for any other purpose, and in fact Applicant can find no reference whatsoever to the signal gradient in Vandehey. Vandehey is completely silent on the question of signal gradient. Further, there is no suggestion or indication in Vandehey that the point (93) following

the “gradient” (95) has, in itself, any particular significance as to when a defibrillation voltage (shock) should be given.

This contrasts strongly with the present invention where the gradient is a primary factor and, in conjunction with the maxima and minima, determines in real time precisely when such a shock should be given. Thus the object of the present invention is to determine the precise moment to apply a shock to a patient, and not simply to decide whether a patient should be defibrillated. Since Vandehey works by signal storage and post processing, it is quite clearly incapable of operation in real time in order to indicate the instant that a shock should be given. Thus Vandehey simply looks to see whether the patient is suitable for defibrillation, not when the individual shocks should be given. It looks for maxima and minima but does not at any point determine the gradient between them.

In clinical terms Vandehey identifies whether or not a given patient’s ECG (cardiac rhythm) is life threatening and indeed whether or not a terminating shock is required. The present invention, however, makes the assumption that this decision has already been made and that the patient does require life saving shock therapy. Given that the patient’s rhythm is life threatening, then the present invention provides a method that identifies the optimum instant within the rhythm to apply the shock therapy. Vandehey assumes that the shock can be given anywhere within the rhythm, as employed by current standard of patient care. The present invention however works on the theory that there is an optimum instant where a critical mass of cardiac tissue can be depolarized to interrupt the life threatening or abnormal rhythm, the use of the gradient between the thresholds being crucial to the correct identification of this optimum instant. Furthermore, while delivering the shock (repeatedly) at any random instant can and does work, identifying the optimum instant results in the patient’s abnormal rhythm being terminated earlier and with less required energy, thereby providing a better prognostic outcome.

KenKnight discloses delivering a defibrillator shock to a patient during an up-stroke portion of an ECG cycle. However, it is to be noted that the shock is given during the up-stroke, not at the next following ECG peak as required by the present invention. Further, like Vandehey, KenKnight takes no cognizance of the gradient of the up-stroke. Therefore, even the

combination of Vandehey and KenKnight does not disclose the present invention since neither is concerned with the gradient of the ECG signal and neither gives a shock of an ECG peak following a gradient within certain gradient limits. Therefore, Applicant respectfully submits that the claims as now amended are patentably distinguished over the cited art. Reconsideration and withdrawal of the rejection is requested.

Claims 6 to 11 were rejected under 35 U.S.C. 103(a) as unpatentable over Vandehey (US 4,919,144) in view of KenKnight et al. (US 6,112,117) and further in view Cameron et al. (5,607,454).

As discussed above, independent claims 1 and 13, and claims dependent therefrom, are allowable over Vandehey and KenKnight. Cameron fails to provide the insufficiencies of Vandehey and KenKnight. Accordingly, claims 6 to 11 are allowable as depending from allowable claim 1 and independently allowable for novel and nonobvious matter contained therein. Reconsideration and withdrawal of the rejection is requested.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is found that that the present amendment does not place the application in a condition for allowance, applicant's undersigned attorney requests that the examiner initiate a telephone interview to expedite prosecution of the application.

If there are any fees resulting from this communication, please charge same to our Deposit Account No. 16-2326.

Respectfully submitted,

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